IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

NEWPORT NEWS DIVISION

SOLSYS MEDICAL, LLC, Plaintiff, - against - **ORGANOGENESIS, INC.**, Defendant.	**Case No.: 4:18-CV-00030-HCM-RJK**

OPPOSITION TO
DEFENDANT'S MOTION TO DISMISS

INTRODUCTION

Plaintiff and Defendant market competing skin substitutes for the treatment of hard-to-heal wounds. Defendant recently conducted a highly flawed study that purported to show that its product, Apligraf®, was more effective than Plaintiff's product, TheraSkin®. Among the many problems with the study, the wounds treated with TheraSkin may have been worse than those treated with Apligraf; Apligraf was applied more frequently than TheraSkin; the study purported to evaluate how long it took each product to completely close the wounds but actually evaluated only how long it took the wounds to reach a specified, and arbitrarily selected, size; and the study didn't account for other characteristics of the patients (such as other illnesses) that could skew the results. Notably, the individuals conducting the study were all affiliated with Defendant, including a current member of Defendant's Board of Directors, current and former employees of the Defendant, and Defendant's paid consultants.

Based on that highly flawed study, Defendant created an advertisement that not only touted the false conclusions of the study but also added additional false and misleading claims. Defendant then circulated the advertisement, with a link to the study, to numerous actual and potential customers, including hospitals, wound care clinics and physicians to encourage them to purchase and use Apligraf rather than TheraSkin. As a result, Plaintiff has suffered, and continues to suffer, irreparable harm.

Defendants make much of the fact that the study was published in a peer reviewed journal. But false and misleading advertising is not immune from the Lanham Act merely because it references a publication in a peer reviewed journal.

Because Plaintiff has adequately alleged all of the elements of a Lanham Act claim, as well as all of the elements of a claim for false advertising under the Virginia Code, Defendant's motion to dismiss should be denied.

STATEMENT OF FACTS

Plaintiff and Defendant market competing skin substitutes: Apligraf and TheraSkin.

Defendant's Apligraf Product

Defendant Organogenesis markets a skin substitute called Apligraf, which is used to treat chronic wounds including diabetic foot ulcers ("DFUs") and venous leg ulcers ("VLUs"). Apligraf is made from substances extracted from the tendons of cattle and the foreskins of human infants.

In order to receive approval from the Food and Drug Administration ("FDA") to market Apligraf, Organogenesis submitted an application for premarket approval ("PMA"). The PMA included data from a 297 patient prospective randomized controlled trial (the "Organogenesis Pivotal Trial"). This study compared the use of Apligraf and compression to the use of zinc paste gauze and compression in VLUs of greater than one month duration that had not adequately responded to conventional therapy.

Based on the results of the study, the FDA approved Apligraf as a medical device in 1998.

Plaintiff's TheraSkin Product

In 2009, Solsys (which, at the time was called Soluble Systems, LLC) began to market a competing FDA-regulated skin substitute called TheraSkin. Like Apligraf, TheraSkin is used to treat chronic wounds including DFUs and VLUs. TheraSkin is made from cryopreserved human skin. Unlike Apligraf, TheraSkin does not include animal-derived or human cultured cells or tissues.

Post-market studies of TheraSkin have demonstrated the product's safety and effectiveness in treating both DFUs and VLUs. For example, a retrospective clinical study of 188 patients seen at the Inova Wound Center in Mount Vernon, Virginia, found that approximately

60% of DFU and VLU wounds had closed after 12 weeks of treatment with TheraSkin, and roughly 75% of VLUs and DFUs had closed after 20 weeks of treatment with TheraSkin. Like the Organogenesis Pivotal Trial, this TheraSkin study defined wound "closure" as the complete epithelialization (i.e., complete coverage of the wound with new skin cells, an essential component of wound healing) of the wound without drainage.

Defendant's Flawed Retrospective Study

In 2015, Organogenesis funded a retrospective study (the "Organogenesis Retrospective Study" or the "Study") that purported to compare the effectiveness of Apligraf and TheraSkin in the treatment of VLUs. The authors of the study were all affiliated with Organogenesis and included a current Organogenesis Board member as well as current and former employees of Organogenesis and paid consultants of Organogenesis.

This study differed in a number of significant ways from the Organogenesis Pivotal Trial. One of the biggest differences is that the Organogenesis Pivotal Trial was a prospective randomized clinical trial, in which patients with equivalent wounds were randomly selected to receive treatment with either Apligraf or zinc paste gauze and the healing of the two groups was compared over time. In contrast, the Organogenesis Retrospective Study was "retrospective," meaning the study used existing data taken from medical records of patients who had been previously treated with either Apligraf or TheraSkin.

There are numerous problems with the Organogenesis Retrospective Study. First, the wounds treated with TheraSkin appear to have been worse at the outset of the study than the wounds treated with Apligraf. The study shows that prior to treatment, the wounds treated with TheraSkin had been present an average of three months longer than the wounds treated with Apligraf, suggesting that they were more serious, slower healing wounds. This completely

undermines the entire study because it suggests that these wounds would have taken longer to heal regardless of what treatment was used.

Similarly, the Study provided no information about why doctors chose to treat patients with Apligraf or TheraSkin. The fact that TheraSkin was used on wounds that had been present an average of three months longer suggests that doctors could have selected TheraSkin for more serious or persistent wounds, which also could have affected the results. The failure to control for this potential bias (as well as for numerous others) was a fundamental flaw that undermines the conclusions of the study.

Second, the Organogenesis Retrospective Study defined wounds as "closed" when they were still open, as long as the opening was no larger than .25cm^2. The advertisement that Defendant created discussing the study similarly, and prominently, uses the word "closed" without disclosing the arbitrary definition used in the Study or that the Organogenesis Pivotal Trial used a different, widely accepted, definition.

Third, the Organogenesis Retrospective Study failed to account for underlying comorbidities of the patients. That is, it did not consider whether some of the patients had other medical conditions that would make wounds heal more slowly or to attempt to control for this factor.

Fourth, Apligraf was applied far more frequently than TheraSkin in the Organogenesis Retrospective Study. The Study states that patients using Apligraf required multiple applications of the product significantly more often than the patients using TheraSkin. In other words, Apligraf may have appeared to be more effective, but only because far more of it was used. The Study made no attempt to control for this difference.

Fifth, the authors of the Organogenesis Retrospective Study state that the supposedly more rapid healing with Apligraf suggests that Apligraf would be cheaper to use, but in reaching this conclusion they completely fail to take into account the fact that Apligraf required more applications than TheraSkin.

In addition, the Organogenesis Retrospective Study contains a variety of false statements and negative implications about TheraSkin. First, it implies that only Apligraf is regulated by FDA, stating:

> ***Apligraf*** . . . is a bioengineered living cell therapy that contains human neonatal keratinocytes and fibroblasts in an extracellular matrix (ECM) of bovine, human collagen, and other ECM proteins. It is ***one of only three skin substitute products approved by the Food and Drug Administration (FDA) as a "wound treatment."*** In the United States, wound treatments are approved via the FDA premarket approval process, which mandates the most rigorous FDA review procedures, including approval of at least one pivotal clinical trial to support its indication. [Apligraf] is FDA-approved for the treatment of both diabetic foot ulcers and VLUs, and currently, it is the only skin substitute approved for the treatment of VLUs. . . .
>
> Another skin substitute on the market is a cryopreserved cadaveric skin allograft . . . ***TheraSkin*** . . . [TheraSkin] is a human skin allograft harvested from tissue donors within 24 [hours] of death. It is processed with cleaning, hair removal, and meshing, and then exposed to antibiotics and reagents. The tissue is cryopreserved in an effort to retain the living cellular and extracellular components. [TheraSkin] is marketed under Section 361 of the Public Health Services (PHS) Act as Human Cells, Tissues, and Cellular and Tissue-based Products (361 HCT/Ps). Under this regulatory pathway, [TheraSkin] ***is considered a "wound covering" and adheres to the standards set forth for the tissue bank industry. Furthermore, clinical data establishing efficacy or safety are not required.***

Treadwell, T., *et al.*, *Comparative Effectiveness of a Bioengineered Living Cellular Construct and Cryopreserved Cadaveric Skin Allograft for the Treatment of Venous Leg Ulcers in a Real-World Setting*, Advances in Wound Care, Vol. 7, No. 3 (2017) at 70 (attached as Exhibit 1 to Complaint) (emphasis added).

In reality, both Apligraf and TheraSkin are subject to stringent FDA requirements that are tailored to their respective properties and methods of manufacture. Unlike TheraSkin, which is a minimally manipulated human tissue-based product (*see* 21 CFR Part 1271), Apligraf is an extensively processed medical device that incorporates both human and non-human cellular and non-cellular components. Summary of Safety and Effectiveness Data for Apligraf™ (Graftskin) (P950032), available at https://www.accessdata.fda.gov/cdrh_docs/pdf/P950032B.pdf

The FDA imposes more restrictions on the sale and distribution of Apligraf than on the sale and distribution of TheraSkin because Apligraf is classified as a high-risk medical device. *See* 21 USC 360c (a) (C) and 21 USC 360e. Thus, the implication in the study that Apligraf is safer and/or more clinically effective for the treatment of wounds because it has more FDA oversight is plainly false.

Second, as can be seen in the passage quoted above, the Organogenesis Retrospective Study falsely characterizes TheraSkin as a "wound covering" (in contrast to a wound treatment) implying that TheraSkin, unlike Apligraf, does not have therapeutic effect. In fact, pursuant to applicable FDA regulations, TheraSkin is intended to perform any "homologous use," i.e., any use that it would perform in its native state, including, in the case of human skin, wound healing.

The Organogenesis Retrospective Study also erroneously implies that the quality of TheraSkin will vary based on the differences in the donors from whom the tissue was derived, and that such variation will adversely affect TheraSkin's therapeutic capacity, stating:

> As a bioengineered product, the cells in [Apligraf] are well characterized for purity and potency, and manufactured to ensure lot-to-lot consistency. As a donated tissue product, [TheraSkin] contains the native cells from human skin but the properties of the tissue will be variable from donor-to-donor and depend on donor age, health, and location of harvested tissue.

Treadwell, T., *et al*. at 70. In reality, there are strict screening criteria used to minimize variation between sources of the tissue used to manufacture TheraSkin, including procuring of tissue from specific areas of the body and excluding donors based on age or health conditions.

Defendant's False Advertisement

After completing the highly flawed Organogenesis Retrospective Study, Organogenesis created an advertisement (the "Advertisement") and marketing campaign that not only summarized the false conclusions of that study, but also added additional false information to it.

The Advertisement (which is attached to the Complaint as Exhibit 1) incorporated a linked copy of the Organogenesis Retrospective Study. It was widely disseminated via e-mail blasts to hospitals, wound care clinics, health care providers, and other customers for the purpose of influencing their purchasing decisions.

Defendants refer to the Advertisement as a "Cover E-mail," but that is deceptive because the Advertisement did not simply say, "see attached." Rather, it was formatted as a marketing piece and contained assertions and charts that were not part of the Study and that were not actually supported by the Study.

First, the subject heading on the email sending the Advertisement states:

How to Heal More VLUs, Faster

This is a false and deceptive statement because it implies that Apligraf heals wounds more quickly than TheraSkin. But this is not what the Study measured since it did not compare the time to wound closure after treatment with each product, but rather the time to achieve a wound of a specific, arbitrarily-selected size.

Second, the Advertisement states:

> **Apligraf® Does It Again!**
>
> **Similar to Apligraf's VLU pivotal trial,**
> **APLIGRAF CLOSES MORE VLUs, FASTER**
> **IN A COMPARATIVE EFFECTIVENESS STUDY**
>
> **Apligraf Closes More VLUs, Faster Compared to TheraSkin®**

Read together, these statements clearly imply that Apligraf was shown to be more clinically effective than TheraSkin not only in the current study, but also in the Pivotal Trial, meaning the one that supported FDA approval. In fact, it suggests that FDA's decision to approve Apligraf was based on data comparing Apligraf to TheraSkin. As discussed above, this is untrue. There was no previous trial that found Apligraf superior to TheraSkin and the Organogenesis Pivotal Trial did not involve a comparison to TheraSkin.

In addition, these statements imply that the current Study was a confirmatory clinical trial conducted in the same manner, and with the same protocols (and FDA stamp of approval) to control for bias as the initial pivotal trial. This is simply false.

Third, the Advertisement contains three charts with the following headings:

> **Apligraf closed more VLUs by week 12**
>
> **Apligraf closed more VLUs by week 24**
>
> **Apligraf closed more VLUs faster**

These assertions are all unsupported by the Study because, as discussed above, the Study was flawed, rendering its conclusions unsupported, and the Study did not actually study the "closure" of VLUs.

Fourth, the Advertisement states:

Apply Apligraf to stimulate healing and close more VLUs, faster

Again, nothing in the Study supports the claim that Apligraf will "close more VLUs, faster," because the Study was flawed, and because it did not compare the time it took for the VLUs to fully "close."

SUMMARY OF ARGUMENT

The Study and Advertisement Are Commercial Speech

The Lanham Act prohibits false or misleading representations of fact in commercial advertising. To fall within the definition of "commercial advertising," a representation must, among other things, be "commercial speech." In determining whether a message is "commercial speech," the Fourth Circuit considers whether it: (1) is economically motivated; (2) promotes a specific product; (3) is an advertisement; and (4) was placed in a commercial context and directed at the providing of services rather than toward an exchange of ideas. A for-profit company is generally presumed to have primarily economic motivations for its speech, even when that speech addresses issues of public concern.

In the present case, Defendant funded a highly flawed study to compare its product to that of its competitor. Defendant then sent the Study, and an Advertisement inaccurately describing its results, to numerous customers in an effort to get them to buy Defendant's product instead of Plaintiff's. Under these circumstances, the distribution of the Study and Advertisement was clearly commercial speech.

Publication in a Journal Does Not Immunize Defendant's Activities

Defendant argues that, even if the Study and Advertisement are commercial speech, because the Study was published in a peer reviewed journal, the Study, its distribution, and the distribution of the Advertisement based on that Study are all protected by the First Amendment

and, as a result, are beyond the reach of a false advertising claim under the Lanham Act. But the case law does not support such an expansive reading of the First Amendment's protection of advertising in Lanham Act cases.

Numerous courts have held that advertisements are not immune from the reach of the Lanham Act simply because they are based on peer reviewed studies. Moreover, some have concluded that even if the initial publication of a peer reviewed study is beyond the reach of the Lanham Act, its redistribution is not. Furthermore, the courts have been particularly reluctant to give any protection to advertisements that, like the Advertisement at issue in the present case, misrepresent the conclusions of peer reviewed studies.

Peer Review Should Not Shield Advertising Campaigns

Defendant's position that any advertising campaign based on a peer reviewed study should enjoy blanket immunity from claims for false advertising under the Lanham Act is not only contrary to the case law but also highly problematic from a public policy perspective. While peer review may have once been a more or less adequate process to ensure that studies were not published unless they adhered to basic scientific standards, this is no longer the case.

Many so called "predatory journals" hold themselves out as having a rigorous peer review process but will actually publish virtually anything as long as the authors pay a publication fee. But these journals are not readily distinguishable from more legitimate journals. And even in legitimate journals, the peer review process is sometimes corrupted, with authors using pseudonyms to serve as their own reviewers or repeatedly reviewing one another's works. Because the peer review process lacks transparency even at legitimate journals, problems like this are difficult or impossible for even a discerning reader to detect.

These concerns about the integrity of the peer review process highlight the problem that could be created by adopting the approach that Defendant advocates. Under that approach, a corporation could evade liability for false advertising by commissioning a flawed research study, having it published in a "peer reviewed" journal that did not subject it to actual review, and then basing its advertising campaign on the supposed findings of that study. Such a result is neither desirable nor mandated by the First Amendment.

The Study and Advertisement Were Literally False

To prevail on a false advertising claim under the Lanham Act, a plaintiff must show either that a statement is "literally false" or that it is likely to mislead and confuse consumers. A literally false statement can be explicitly false on its face, or false by "necessary implication." A plaintiff's burden in establishing that a statement is literally false varies depending on whether the statement was an "establishment claim." An establishment claim is one in which a defendant claims that a scientific study "establishes" something about a product. In such a case, a plaintiff does not have to prove that the defendant's claim about the product is false, but only that the tests or studies relied upon are not sufficiently reliable to permit one to conclude with reasonable certainty that they established the claim made. In the present case, Plaintiff has adequately alleged that the Advertisement contains explicitly false statements and statements that are false by implication. Furthermore, because Plaintiff has adequately alleged that the Study does not support the conclusions in either the Study itself or the Advertisement, Plaintiff has met its burden of alleging that the Defendant's comparative claims are literally false.

Consumer Deception is Presumed

Evidence of consumer deception is not required when the claims made by a defendant are literally false. In those cases, consumer deception is presumed. Defendant argues that the

physicians who received Defendant's Advertisement were too sophisticated to be deceived, but a district court has recently rejected this exact argument, holding that a "manufacturer's selective promotion of favorable scientific information could be potentially misleading even to sophisticated and experienced doctors" and that the plaintiff was entitled to a presumption of consumer deception because the statements were literally false. Similarly, in the present case, the statements at issue are literally false and consumer deception should therefore be presumed.

Plaintiff Adequately Alleges the Elements of the Virginia Law

Plaintiff has also adequately alleged a claim of false advertising under the Virginia Code. Defendant argues that Plaintiff has not adequately alleged that it suffered an actual loss as a result of Defendant's conduct. But that argument simply ignores the various allegations throughout the Complaint alleging loss of reputation, goodwill and customers as a result of Defendant's unlawful conduct.

Retraction of the Advertisement is an Appropriate Remedy

Finally, Defendant argues that an order requiring it engage in corrective advertising has no support in law. But the Fourth Circuit recently upheld a district court order imposing just such relief. The court held that "prior restraints prohibiting false and misleading commercial speech are constitutional" and that the First Amendment "allows the district court to require [the defendant] to issue a retraction email."

Defendant's Motion Should be Denied

For all of these reasons, Defendant's motion should be denied.

ARGUMENT

I. DISSEMINATION OF THE STUDY AND ADVERTISEMENT WAS COMMERCIAL SPEECH.

A. The Study and Advertisement Fall Within the Definition of Commercial Speech.

The Lanham Act "prohibits false or misleading facts, or representations of fact, 'in ***commercial advertising*** or promotion' that misrepresent the quality of another person's goods.'" *Handsome Brook Farm, LLC v. Humane Farm Animal Care, Inc.*, 700 F. App'x 251, 255 (4th Cir. 2017) (quoting 15 U.S.C. § 1125(a)(1)(B)) (emphasis added). The Fourth Circuit has held that to constitute "commercial advertising or promotion" a representation must be: (1) ***commercial speech***; (2) made for the purpose of influencing consumers to buy goods or services; and (3) sufficiently disseminated to the relevant purchasing public to constitute advertising or promotion within that industry. *Handsome Brook Farm,* 700 F. App'x at 257 (*citing Gordon & Breach Sci. Publishers v. Am. Inst. of Physics*, 859 F. Supp. 1521, 1536 (S.D.N.Y. 1994)) (emphasis added).

In determining whether a message is "commercial speech," the Fourth Circuit considers whether it: (1) is economically motivated; (2) promotes a specific product; (3) is an advertisement; and (4) was placed in a commercial context and directed at the providing of services rather than toward an exchange of ideas. *Handsome Brook Farm,* 700 F. App'x at 257-58. The first prong asks whether the party "hoped to realize an economic gain when disseminating its message." *Id.* at 258. A for-profit company is generally presumed to have primarily economic motivations for its speech, even when that speech addresses issues of public concern. *See id.* Thus, for instance, "an educational seminar hosted by a corporation that sells houseware, where attendees both may purchase the products and learn 'how to be financially responsible and how to run an efficient home,' is still treated as commercial speech." *Id.* at 261

(quoting *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473-74, 109 S. Ct. 3028, 106 L. Ed. 2d 388 (1989)).

Here, Organogenesis funded a highly flawed study to compare its skin substitute, Apligraf, with that of its competitor. All of the researchers were affiliated with Organogenesis. The Study was then circulated, together with an accompanying Advertisement that inaccurately described the results of the Study, to numerous customers and potential customers in an attempt to increase sales of Apligraf. Under these circumstances, there can be no question that circulation of the Study and Advertisement were commercial speech made for the purpose of influencing consumers to buy goods and that they were sufficiently disseminated to the relevant purchasing public to constitute advertising or promotion within that industry. *See Handsome Brook Farm,* 700 F. App'x at 262 (finding that an email sent to thirty-six retailers was sufficiently disseminated to be an attempt to penetrate the relevant market).

B. Defendant's Activities Are Not Immunized From Lanham Act Liability by the Fact That the Study Was Published in a Peer Reviewed Journal.

Defendant relies heavily on the Second Circuit case *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d Cir. 2013) to argue that its conduct is beyond the reach of the Lanham Act. In *ONY*, the court held that the contents of a peer reviewed article were not subject to a claim for false advertising under the Lanham Act. The court also held that the secondary distribution of promotional materials that accurately described the conclusions of the article could not form the basis of *a claim for tortious interference.*

The *ONY* case did not address whether secondary distribution of a peer reviewed study for commercial purposes could form the basis of liability *under the Lanham Act* (as opposed to a tortious interference theory of liability). Moreover, the case has been criticized for providing too much protection for the secondary distribution of study findings. *See Recent Cases*, 127 Harv. L.

Rev. 1815, 1819 (2014) ("[T]he court did not recognize that dissemination of the published article for marketing purposes should be considered separately as a secondary act of speech that may provide a basis for liability under the Lanham Act. Given the ongoing debate on the reliability of corporate-funded studies, especially in the pharmaceutical industry, the court may have provided a shield of superficially scientific speech behind which unscrupulous corporations may hide.").

Moreover, *ONY* limited protection for the secondary distribution (in the context of the tortious interference claim) to situations in which materials distributed *accurately* described the conclusions of the study. *ONY*, 720 F.3d at 499. In the present case, Plaintiff alleges that the Advertisement did *not* accurately reflect the conclusions of the Study. *See* Compl. ¶¶ 30-47.

Notably, other Lanham Act cases have taken a more limited view of the protection provided by the First Amendment to the distribution of published studies and promotional materials based on those studies. For instance, in *Eastman Chem. Co. v. PlastiPure, Inc.*, 775 F.3d 230 (5th Cir. 2014), the Fifth Circuit held that advertisements based on a peer reviewed study fell within the reach of the Lanham Act. The court distinguished *ONY*, stating:

> The plaintiff in *ONY* sought to enjoin statements made within the academic literature and directed at the scientific community. In that context, the Second Circuit concluded that the defendants' statements should be treated as opinions, else the prospect of defamation liability would stifle academic debate and trench upon *First Amendment* values. . . . Here, in contrast, Eastman did not sue Appellants for publishing an article in a scientific journal. Rather, Eastman sought to enjoin statements made in commercial advertisements and directed at customers. . . . In this commercial context, the *First Amendment* is no obstacle to enforcement of the Lanham Act.

Id. at 236.

The court went on to note that the advertisements at issue were not immune from the Lanham Act simply because they were based on a peer reviewed study, stating:

> [I]t is of no moment that the commercial speech in this case concerned a topic of scientific debate. Advertisements do not become immune from Lanham Act scrutiny simply because their claims are open to scientific or public debate. Otherwise, the Lanham Act would hardly ever be enforceable—"many, if not most, products may be tied to public concerns with the environment, energy, economic policy, or individual health and safety." *Cent. Hudson*, 447 U.S. at 563 n.5. The Supreme Court has "made clear that advertising which links a product to a current public debate is not thereby entitled to the constitutional protection afforded noncommercial speech." *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 68, 103 S. Ct. 2875, 77 L. Ed. 2d 469 (1983) (internal quotation marks omitted); *see also* Recent Case, 127 Harv. L. Rev. 1815, 1819 (2014) ("Dissemination of a scientific article as part of a company's marketing campaign is for promotional purposes and therefore qualifies as commercial speech.").

Id. at 236-37.

Similarly, in *Mimedx Grp., Inc. v. Osiris Therapeutics, Inc.*, 2017 U.S. Dist. LEXIS 114105 (S.D.N.Y. July 21, 2017) the court concluded that a press release and brochure summarizing the results of a peer reviewed study were commercial speech, and subject to the Lanham Act, despite the fact they addressed topics of scientific debate, stating:

> "Pure commercial speech 'does no more than propose a commercial transaction.'" *Enigma Software Grp. USA*, 194 F. Supp. 3d at 293-94 (quoting *Bolger* v. *Youngs Drug Prods. Corp.*, 463 U.S. 60, 66, 103 S. Ct. 2875, 77 L. Ed. 2d 469 (1983)). Meanwhile, "a 'hybrid' communication, *i.e.*, one that combines commercial and non-commercial elements, may nonetheless be 'commercial' where [i] it is an advertisement; [ii] it refers to a specific product or service; and [iii] the speaker has an economic motivation for the speech." *Id.*; *see Bolger*, 463 U.S. at 66-67 (holding that pamphlets containing information about sexually transmitted disease were "properly characterized as commercial speech," despite their discussion of important social issues, because they were advertisements that referenced the publisher's products and the publisher had a commercial motivation for disseminating them).
>
> Here, the ***statements in the Press Release and the Brochure qualify as commercial speech***: They tout the benefits of Defendant's product over Plaintiff's competing product and they are principally directed to a consumer audience, not a scientific one. Contrary to Defendant's assurance, *ONY* does not alter the calculus here.

Id. at *17-18 (emphasis added).

In *Biolase, Inc. v. Fotona Proizvodnja Optoelektronskih Naprav D. D.*, 2014 U.S. Dist. LEXIS 195010 (C.D. Cal. 2014) (June 4, 2104), a court addressing this issue focused on whether the plaintiff had alleged that the secondary materials accurately reflected the findings of the study. There, the plaintiff alleged that its competitor had used false and misleading advertising and that the journal article on which the advertising was based was flawed. The court, citing *ONY*, initially dismissed plaintiff's complaint. *Id.* However, when the plaintiff subsequently filed an amended complaint alleging that the conclusions in the article did not support the claims made in the advertisements, the court held that the plaintiff had adequately stated a claim for false advertising, noting that in *ONY*, the alleged false advertising appeared to be "accurate restatements" of conclusions in scientific journal articles. *Id.*

In *Gordon & Breach Sci. Publrs. S.A. v. Am. Inst. of Physics*, 859 F. Supp. 1521 (S.D.N.Y. 1994), the court held that *distribution* of articles can constitute "commercial speech" even when the articles themselves are not commercial speech. There, the court stated:

> While we have held that non-profit organizations must be free to publish on any topic, even those that redound to their financial benefit, without fear of Lanham Act liability, the same does not apply to subsequent (or, occasionally, prior) promotional uses of that speech. The situation is similar to that of a restaurant or movie review or a *Consumer Reports* product report. While the restaurant review or product report itself constitutes exactly the type of "consumer or editorial comment" that "raise[s] free speech concerns" and which Congress explicitly intended to exclude from Section 43(a)'s scope, *see supra* p. 28, a restaurant clearly engages in commercial speech when it posts the New York Times review in its window, and General Motors engages in commercial speech when it announces in a television commercial that its car was ranked first by *Consumer Reports.* The *Consumer Reports* article, of course, does not somehow become commercial speech; rather, G.M.'s *use* of the article is commercial speech. Consequently, G.M. may be sued under the Lanham Act, and *Consumer Reports'* testing methodology may become subject to judicial scrutiny to determine whether G.M. "used in commerce" a "false or misleading representation of fact." We do not reach a different conclusion here merely because the secondary user of the articles is the same entity that published them in the first place.

Id. at 1544-45.

Similarly, in *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384 (D.N.J. 2009), the court held that although the publication of a peer-reviewed scientific article did not constitute commercial speech, the secondary dissemination *of the article itself* in a press release did constitute commercial speech. The court stated:

> Accordingly, because GEH's advertising campaign using the NEPHRIC article is clearly promotional in nature, similar to the advertising in [*Gordon & Breach Science Publishers v. Am. Inst. of Physics, 859 F. Supp. 1521, 1537 (S.D.N.Y. 1994)*] and [*Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), vacated in part on other grounds 340 U.S. App. D.C. 108, 202 F.3d 331 (D.C. Cir. 2000)], the Court finds that ***Defendants' secondary distribution of the NEPHRIC article does constitute a form of commercial speech***.

Id. at 459 (emphasis added).

A similar issue arose in *Semco, Inc. v. Amcast, Inc.*, 52 F.3d 108 (6th Cir. 1995). There, the president of Amcast submitted an article for publication in a trade journal. After the article was published, Amcast obtained reprints, made numerous copies, and used the article as a promotional brochure at trade shows. Addressing the question of whether the article was commercial speech for purposes of a Lanham Act claim, the court noted initially that: "Speech need not closely resemble a typical advertisement to be commercial." *Id.* at 112. The court further stated that: "The district court in this case viewed the Kopp article as more article than advertisement, but we cannot ignore the promotions of Amcast, also evident in the article, which do not contribute to its intellectual or technical value." Thus, the court concluded that "***the alleged misrepresentations contained in the Kopp article represent commercial speech*** and are actionable under the Lanham Act." *Id.* at 114 (emphasis added).

In *Genzyme Corp. v. Shire Human Genetic Therapies, Inc.*, 906 F. Supp. 2d 9 (D. Mass. 2012) the court held that a press release describing a comparative study was commercial speech, stating:

> In this case, ***while the original presentation of the comparative data*** at the EWGGD convocation ***was protected scientific expression, its secondary dissemination in a press release by Shire HGT was not***. The press release was not a scientific publication, it directly named VPRIV and Genzyme, the two principal competitors in the Gaucher disease enzyme replacement therapy market, and it listed Shire plc's stock symbols on its first line. *See United States v. Harkonen*, 2009 *U.S. Dist. LEXIS 47255, 2009 WL 1578712, at *6 (N.D. Cal. June 4, 2009)* ("That the speech is a press release and not a peer-reviewed publication, that it refers to a specific commercial product on the market . . ., and that it was unquestionably disseminated for commercial benefit (e.g., the first line notes [defendant]'s Nasdaq stock symbol), are allegations that take the speech at issue outside the realm of pure science speech and move it towards the realm of commercial speech."). Like the promotional speech in *Gordon & Breach* and *Bracco*, the press release selectively disseminated information favorable to Shire HGT's VPRIV and unflattering to Genzyme to an audience that included both physicians who prescribe Gaucher disease treatments and patients (e.g., those served by the National Gaucher Foundation) who might request a specific treatment. ***Under the circumstances, Shire HGT's press release may be deemed commercial speech.***

Id. at 16-17 (emphasis added).

Further, the court held that because determining whether the press release contained false statements would require "delving into murky scientific data and analysis" from the underlying study, resolution on a motion to dismiss was inappropriate. The court explained:

> Shire HGT's fallback argument is that even if the press release constituted commercial speech, Genzyme's Verified Complaint fails to allege that it contained literally false statements, impliedly false or misleading statements, or embellished claims, because the press release accurately reported the underlying scientific analysis and results. ***Unless the complained of speech is such that "a court can properly say that no reasonable person could be misled by the advertisement in question,"*** *Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc., 653 F.3d 241, 252 (3rd Cir. 2011),* ***"it is not appropriate to resolve [the issue of the truthfulness of the speech] on a motion to dismiss."*** *World Wrestling Fed'n Entm't, Inc. v. Bozell, 142 F. Supp. 2d. 514, 529 (S.D.N.Y. 2001).* In *Pernod,* the court found that despite the prominent mark "Havana Club," Bacardi's rum labels were not misleading because they clearly stated that the product was "Puerto Rican Rum" that was "distilled and crafted in Puerto Rico." *Pernod, 653 F.3d at 252*. In contrast, ***Genzyme alleges that the press release conveyed the literally false message that VPRIV outperforms Genzyme in improving patient BMD.*** VC ¶ 28. Unlike the clear picture in *Pernod,* ***the veracity of this allegation involves a delving into murky scientific data and analysis, a task that cannot be***

> ***satisfactorily undertaken on a motion to dismiss where the court is largely confined to the allegations of the complaint.***

Id. at 17 (emphasis added).

Defendant starts off its brief with a quote from *Underwager v. Salter*, 22 F.3d 730 (7th Cir. 1994), but that case is not a Lanham Act case and is not comparable to the present case. *Underwager* was a defamation case brought under Wisconsin law by two psychologists who had written books concluding that most accusations of child sexual abuse stem from false memories. One of the plaintiffs routinely served as an expert witness for defendants accused of molesting children. One of the defendants was a psychologist who had given a television interview criticizing the plaintiffs' books and who, using funding from a grant, had drafted an unpublished monograph on the same topic. The other defendant was a former prosecutor who played a tape of the television interview at conferences for prosecutors in child sexual abuse cases.

The plaintiffs in *Underwager* argued that, to prevail on their defamation claim, they did not need to establish "actual malice" (which, the court noted, has nothing to do with "ill will," but rather, means "knowledge that the statement was false, or doubts about its truth coupled with reckless disregard of whether it was false") because defendants were not reporters or publishers. The court disagreed, noting that "[p]sychologists compiling monographs with the aid of research grants, and prosecutors seeking to augment one side's arsenal for trial" do not have the financial resources of newspapers and broadcast stations and that "[e]xposing such persons to large awards of damages is more apt to lead to silence than are comparable awards against media defendants." Thus, the court concluded that the plaintiffs could prevail only if they could show that defendants acted with actual malice.

Finding that the defendants acted without malice, the court affirmed the lower court's grant of summary judgment in favor of the defendants. The court stated (immediately prior to the passage quoted by Defendants in the present case):

> Both [of the defendants] came to believe that [the plaintiff who serves as an expert witness] is a hired gun who makes a living by deceiving judges about the state of medical knowledge and thus assisting child molesters to evade punishment. Persons who hold such opinions cannot be expected to look kindly on their subjects, and the law certainly does not insist that they shut up as soon as they are challenged. [The plaintiffs] cannot, simply by filing suit and crying "character assassination!", silence those who hold divergent views, no matter how adverse those views may be to plaintiffs' interests.

Id. at 736 (citation omitted).

Underwager is not equivalent to the present case. In that case, the defendants did not seek to sell a product. Rather, they sought to help train prosecutors by explaining the problems that they saw with the research underlying the plaintiffs' books and testimony. Moreover, *Underwager* dealt with individuals with limited funding who were likely to be silenced by the prospect of large damages awards.

In contrast, Defendant in the present case is a corporation that undertook a flawed research study that yielded invalid results, misrepresented the Study's conclusions in an advertisement, and then widely disseminated the article and advertisement in an effort to get purchasers to buy its product rather than a competitor's product. Defendant's actions are commercial speech and are well within the reach of the Lanham Act's prohibition on false advertising.

C. Immunizing Advertisements That Are Based on Peer Reviewed Studies Would Create a Massive Loophole in the Lanham Act's Prohibition on False Advertising.

Defendant argues that any advertising campaign based on a peer reviewed study should be immune from claims for false advertising under the Lanham Act even if the claims made in

the study and advertisements are completely false. They hypothesize a world in which ideas can be fought with more ideas and the courts can depend on the peer review process to guarantee that basic scientific standards are followed and that truly bad research isn't published. But if such a world ever existed, it no longer does.

In reality, while some peer reviewed journals do impose legitimate controls on what gets published, many others will publish virtually any article as long as the authors pay a fee. An article discussing this problem noted that a spoof paper was recently accepted into an ostensibly peer reviewed journal despite the fact that the paper "was a simple repetition of the words 'Get me off your f***ing mailing list' for 10 pages, complete with section headings and appropriate figures." Bonnie Swoger, *Is this peer reviewed? Predatory journals and the transparency of peer review."* Scientific American (Nov. 26, 2014) (providing link to spoof paper).[1] "The paper was accepted by the *International Journal of Advanced Computer Technology*, which promotes its tiered and highly selective review process on its website." *Id.*

The Scientific American article goes on to explain:

> Journals like IJACT are often called "predatory journals," journals that accept anything, as long as you are willing to pay the publication fee. . . . [T]o a novice, a journal like IJACT looks a lot like other scientific journals . . . Predatory publishers can get away with claiming a rigorous review process because traditional peer review is shrouded in secrecy. The reader sees the same amount of evidence about the peer review process from both high quality journals and predatory journals: a statement about the process on their website. . . . A skeptical reader might try to find out more about the journal: where is it indexed, what metrics are associated with it, who is on the editorial board? But a typical user won't go through all of this effort and [will] accept the piece at face value. And even a skeptical reader would find it impossible (at most journals) to understand the peer review standards employed or the criteria reviewers use: this information is rarely available to users.

[1] https://blogs.scientificamerican.com/information-culture/is-this-peer-reviewed-predatory-journals-and-the-transparency-of-peer-review/

Id.

Even in legitimate journals, peer review does not always operate as one might expect. Many journals allow authors to recommend independent reviewers, which can obviously compromise the objectivity of the process. C. Ferguson, A. Marcus & I. Oransky *Publishing: The peer-review scam; When a handful of authors were caught reviewing their own papers, it exposed weaknesses in modern publishing systems. Editors are trying to plug the holes.* Nature, November 26, 2014.[2] Moreover, there have been a number of instances of massive peer review rigging, in which authors reviewed their own papers using pseudonyms or reviewed one another's works as part of a "peer review ring." *Id.*

Given these concerns about the integrity of the peer review process, as well as "the ongoing debate on the reliability of corporate-funded studies, especially in the pharmaceutical industry," granting blanket immunity to any advertisement that is based on the findings of a peer reviewed article would raise grave concerns as it could provide "a shield of superficially scientific speech behind which unscrupulous corporations may hide." See *Recent Cases*, 127 Harv. L. Rev. 1815, 1819 (2014).

Under this scenario any corporation could immunize a dishonest marketing campaign simply by commissioning a misleading research study and paying a fee to have it published in a dubious "peer reviewed" journal. Such a result is neither desirable nor mandated under the First Amendment.

II. THE STUDY AND ADVERTISEMENT WERE LITERALLY FALSE.

A Lanham Act plaintiff can prevail on a false advertising claim either by showing that a statement is "literally false," or by showing that, although literally true, it is likely to mislead and

[2] http://www.nature.com/news/publishing-the-peer-review-scam-1.16400

to confuse consumers given the merchandising context. *First Data Merch. Servs. Corp. v. SecurityMetrics, Inc.*, 672 F. App'x 229, 234 (4th Cir. 2016) ("A plaintiff can establish the first element by showing an advertisement is either (a) literally false or (b) literally true but likely to mislead or confuse consumers.") (*citing C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F.3d 430, 434 (4th Cir. 1997)); *PBM Prods., LLC v. Mead Johnson & Co.*, 639 F.3d 111, 120 (4th Cir. 2011).

A literally false message may be conveyed explicitly or by "necessary implication" when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated. *PBM Prods.*, 639 F.3d at 120 (*quoting Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 274 (4th Cir 2002)). Thus, "a claim of literal falsity by necessary implication is viable where the plaintiff's asserted conclusion 'necessarily flowed from the ad's statements.'" *Trex Co. v. CPG Int'l LLC*, Civil Action No. 5:17-cv-00005, 2017 U.S. Dist. LEXIS 120317, at *24-29 (W.D. Va. Aug. 1, 2017) (*quoting Design Resources, Inc. v. Leather Indus. of Am.*, 789 F.3d 495, 503 (4th Cir. 2015).

In articulating a plaintiff's burden in establishing that a claim is literally false, courts distinguish between "establishment claims" and "non-establishment claims." *See, e.g., Church & Dwight Co. v. Clorox Co.*, 840 F. Supp. 2d 717, 722-23 (S.D.N.Y. 2012). An establishment claim is one in which the defendant claims that a scientific study "establishes" something about a product. In a case involving establishment claims, a plaintiff does not have to prove that the defendant's claims are false, but only that the tests or studies relied upon "are not sufficiently reliable to permit one to conclude with reasonable certainty that they established the claim made." *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1548-49 (2d Cir. 1991) (citations and internal quotation marks omitted). Thus, the Fourth Circuit has stated:

> When an advertising claim of favorable fact either expressly or impliedly asserts that the fact is test or study-validated, the fact of the validation becomes an integral and critical part of the claim. Such a claim may therefore be proven literally false by showing only that the test asserted to validate it did not in fact do so.

C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, Ltd. P'ship, 131 F.3d 430, 435 (4th Cir. 1997). *See also, e.g., Church & Dwight*, 840 F. Supp. 2d at 722-23 ("Where, as here, scientific or technical evidence is said to establish an advertiser's claim (a so-called 'establishment claim'), a plaintiff can prove literal falsity by showing that the test 'did not establish the proposition for which [it was] cited' because it is either 'not sufficiently reliable to permit a conclusion' or 'simply irrelevant.'"); *Osmose, Inc. v. Viance, LLC*, 612 F.3d 1298, 1310 (11th Cir. 2010) ("Osmose, as a plaintiff challenging "tests prove" or "establishment" claims, does not have to affirmatively prove that Viance's safety concerns are false; rather, Osmose has to prove only that Viance's tests do not support Viance's conclusions."); *Alpo Petfoods, Inc. v. Ralston Purina Co.*, 720 F. Supp. 194, 213 (D.D.C. 1989) ("representations found to be unsupported by accepted authority or research or which are contradicted by prevailing authority or research, may be deemed false on their face and actionable under Section 43(a) of the Lanham Act."), *aff'd in part, rev'd in part on other grounds*, 286 U.S. App. D.C. 192, 913 F.2d 958 (D.C. Cir. 1990); *Procter & Gamble Co. v. Chesebrough-Pond's Inc.*, 747 F.2d 114, 119 (2d Cir. 1984) ("To prove such falsity Chesebrough assumed the burden of showing that the tests referred to by P&G were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited."). As the Eighth Circuit has explained:

> False advertising decisions in other circuits have consistently distinguished between two types of comparative advertising claims: "my product is better than yours," versus "*tests prove* that my product is better than yours." To successfully challenge the first type of claim, a Lanham Act plaintiff must prove that

> defendant's claim of superiority is false. But to successfully challenge the second type of claim, where defendant has hyped the claim of superiority by attributing it to the results of scientific testing, ***plaintiff must prove only "that the tests [relied upon] were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited***." . . . Neither party challenges the standard, and we agree it is a correct application of Lanham Act § 43.

Rhone-Poulenc Rorer Pharm., Inc. v. Marion Merrell Dow, Inc., 93 F.3d 511, 514-15 (8th Cir. 1996) (emphasis added). *See also BASF Corp. v. Old World Trading Co.*, 41 F.3d 1081, 1090 (7th Cir. 1994) ("A plaintiff's burden in proving literal falsity thus varies depending on the nature of the challenged advertisement. Where the defendant's advertisement claims that its product is superior, plaintiff must affirmatively prove defendant's product equal or inferior. Where . . . defendant's ad explicitly or implicitly represents that tests or studies prove its product superior, plaintiff establishes its burden by showing that the tests did not establish the proposition for which they were cited.") (quoting *Castrol Inc. v. Quaker State Corp.*, 977 F.2d 57, 63 (2d Cir. 1992)).

Similarly, the Ninth Circuit has explained that, to prove that an advertising claim is "literally false," a plaintiff "must demonstrate that such tests are not sufficiently reliable to permit one to conclude with reasonable certainty that they established' the claim made." *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997) (citations and internal quotation marks omitted). A plaintiff "may meet this burden either by attacking the validity of the defendant's tests directly or by showing that the defendant's tests are contradicted or unsupported by other scientific tests." *Id.*

The Complaint sufficiently alleges that certain statements in Defendant's Advertisement are explicitly false and false by implication. In addition, the present case involves "establishment claims." Defendant's comparative claims "may therefore be proven literally false by showing

only that the test asserted to validate it did not in fact do so." *C.B. Fleet Co.*, 131 F.3d at 435. Because Plaintiff has adequately alleged that the Study does not support the conclusions stated in the Study itself or in the Advertisement, Plaintiff has met its burden of alleging that the claims are false.

III. CONSUMER DECEPTION IS PRESUMED BECAUSE DEFENDANT'S CLAIMS ARE LITERALLY FALSE.

External evidence of consumer deception is not required when the subject advertisements contain literally false statements. *See In re GNC Corp.*, 789 F.3d 505, 514 (4th Cir. 2015); *Scotts*, 315 F.3d at 273; *Handsome Brook Farm, LLC v. Humane Farm Animal Care, Inc.*, 193 F. Supp. 3d 556, 572 (E.D. Va. 2016).

In *Sanderson Farms, Inc. v. Tyson Foods, Inc.*, 547 F. Supp. 2d 491 (D. Md. 2008), the court stated:

> In this case, unlike in *Scotts Co.*, Plaintiffs have sufficiently demonstrated consumer confusion. There are two distinct aspects to this inquiry, each requiring different quanta of proof: "***If the advertising is literally false, no evidence of consumer confusion is required***. But if the advertising is impliedly false, the plaintiff must present extrinsic evidence of consumer confusion." *Scotts Co.*, 315 F.3d at 274.
>
> Plaintiffs have established the literal falsity of Defendant's unqualified "Raised Without Antibiotics" claim. . . . Having demonstrated the literal falsity of the unqualified "Raised Without Antibiotics" claim and having demonstrated consumer confusion, Plaintiffs have established irreparable harm as to Defendant's unqualified "Raised Without Antibiotics" claim.

Id. at 503-05 (emphasis added).

Defendant argues that the "physicians and other clinicians and scientists" who received the Advertisement are too sophisticated to have been deceived. This precise argument was rejected in *Genzyme Corp.*, where the defendant argued that the plaintiff had "failed to sufficiently allege the necessary element of consumer deception because the physicians who prescribe Gaucher disease treatments are sophisticated experts who are not easily misled."

Genzyme Corp., 906 F. Supp. at 17. The court rejected this argument, noting that "a pharmaceutical manufacturer's selective promotion of favorable scientific information could be potentially misleading even to sophisticated and experienced doctors." *Id.* The court held that the plaintiff was "entitled to the benefit of a presumption of consumer deception because it has alleged the dissemination of literally false statements." *Id.* at 17-18. Thus, the court held that "all of the necessary elements of a Lanham Act violation are sufficiently plead[ed]," and denied the motion to dismiss. *Id.* at 18.

Here, because the Study and Advertisement contain literally false statements, Plaintiff need not provide any evidence of consumer deception.

IV. PLAINTIFF HAS ADEQUATELY ALLEGED A VIOLATION OF VIRGINIA'S FALSE ADVERTISING LAW.

Defendant argues that Plaintiff has failed to state a claim of false advertising under the Virginia Code, Section 18.2–216, because it has not adequately alleged that it has suffered any actual loss as a result of Defendant's conduct. Defendant states that: "Because Solsys's naked assertion that it 'has been injured and is likely to be further damaged by these continuing violations of § 18.2–216 (Compl. ¶ 61) is wholly lacking in factual support, this claim should be dismissed for failure to state a plausible cause of action."

But while Defendant is correct that § 59.1-68.3 of the Virginia Code requires a party to have "suffer[ed] a loss" to have standing, Defendant completely disregards the numerous injuries that Plaintiff alleges in its Complaint, including reputational harm to Plaintiff and lost sales and profits caused by the falsehoods in (and the circulation of) the false Advertisement (Complaint ¶¶ 26 – 28, 31 – 32, 53, 55). The allegations that Defendant's false Advertisement caused such injuries is clearly sufficient for purposes of a claim under Virginia Code Section 18.2–216. *See Maldonado v. Nutri/System, Inc.*, 776

F. Supp. 278 (E.D. Va. 1991) (indicating that loss is a generic and relative term which is synonymous with, or equivalent to, damage, damages . . . [and] injury, and holding that "loss" encompassed not only economic loss, but also personal injuries.") (citing Black's Law Dictionary 851 (5th ed. 1979)).

V. RETRACTION IS AN APPROPRIATE REMEDY AND DOES NOT VIOLATE THE FIRST AMENDMENT.

Defendant mischaracterizes Plaintiff's requested relief. Among other things, Plaintiff seeks "an order requiring Organogenesis to correct any erroneous impression persons may have derived concerning the nature, characteristics or qualities of Apligraf including without limitation the placement of corrective advertising and providing written notice to the public and ***a retraction of any references to or any information regarding*** Organogenesis' Retrospective Study." Compl. at page 15 (emphasis added). Thus, contrary to Defendant's assertion, Plaintiff does not seek to have the journal that published the Study retract the Study. Rather, Plaintiff seeks to have Defendant issue corrective advertising retracting the false claims that it has made.

Contrary to Defendant's assertion that "compulsory retraction and corrective advertising . . . has no support in law," the Fourth Circuit recently imposed ***precisely this remedy*** in *Handsome Brook*:

> ***The First Amendment also allows the district court to require HFAC to issue a retraction email.*** While compelled speech is usually a bold remedy in the context of noncommercial speech, compelled speech is more likely to be constitutionally permissible in the context of commercial speech. . . .
>
> Here, ***compelling HFAC to issue a retraction email is reasonably related to the State's interest in preventing deception of consumers***. HFAC's email informed the grocery stores, who were Handsome Brook's consumers, that Handsome Brook's eggs were not pasture raised or organic. As determined by the district court and largely uncontested here, this email was likely false or misleading. Merely refusing to further disseminate the email reduces the speed by which the false information spreads, but provides no remedy for those who have already read the email and those who share the email with others. Requiring HFAC to issue a retraction email, sent to its initial list of recipients, is a reasonably related

> requirement to ensure that those who received the first email will also receive the retraction email that mitigates the harm the first email caused.
>
> ***Requiring HFAC to issue a retraction email thus comports with the First Amendment.*** Taking into account the irreparable harm that may occur without the injunction and the constitutionality of the injunction's restraints, the balance of equities counsels in favor of the preliminary injunction.

Handsome Brook Farm, 700 F. App'x at 264 (4th Cir. 2017) (emphasis added).

An order prohibiting Defendant from engaging in further dissemination of its false statements is also appropriate. As the court stated in *Handsome Brook*:

> ***[P]rior restraints prohibiting false and misleading commercial speech are constitutional.*** *See, e.g., Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 563, 100 S. Ct. 2343, 65 L. Ed. 2d 341 (1980) ("[T]here can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity."). Because, as determined above, HFAC's email is likely false or misleading commercial speech, the district court may prohibit HFAC from disseminating the email.

Handsome Brook Farm, LLC v. Humane Farm Animal Care, Inc., 700 F. App'x 251, 264 (4th Cir. 2017) (emphasis added).

CONCLUSION

For the foregoing reasons, this Court should deny Defendant's motion to dismiss.

Dated: May 24, 2018

EPSTEIN BECKER & GREEN, P .C.

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filings (NEF) and paper copies of the document will be sent to those indicated as non-registered participants.

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